



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,988	05/16/2005	Lasse Leino	OHMAN-002	1914
32954 7590 12/01/2008 JAMES C. LYDON 100 DAINGERFIELD ROAD SUITE 100 ALEXANDRIA, VA 22314				
EXAMINER				
SIMMONS, CHRIS E				
ART UNIT		PAPER NUMBER		
1612				
MAIL DATE		DELIVERY MODE		
12/01/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/534,988

Applicant(s)

LEINO ET AL.

Examiner

CHRIS E. SIMMONS

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16, 19-22 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16, 19-22 and 28-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' arguments, filed 09/02/2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

Claims 16, 19-22 and 28-30 were rejected under 35 U.S.C. 103(a) as being unpatentable over USP 5,494,676 in view of WO 02/07520. **This rejection is maintained.**

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, applicant argues that the primary reference does not suggest mixing its pharmaceutically acceptable agent (cis-urocanic acid) with a carrier to adjust the pH of the composition to a range of 6.1 to 7.0. This is not persuasive because the motivation for neutral pH is found in the secondary reference, which discloses that less

skin irritation occurs at a relatively neutral pH. Applicant also argues against the secondary reference to highlight the differences between it and the instant claims but any alleged difference is ameliorated by the disclosure of the primary reference. The examiner has relied on the secondary reference's disclosure that less skin irritation occurs when the pH of composition as motivation to make the composition from the primary reference at a relatively neutral pH.

Applicant alleges that even if the secondary reference is analogous prior art, one of ordinary skill in the art would ignore the suggestion that a relatively neutral pH will minimize skin irritation because it has no solid scientific basis. Applicant has submitted 2 references where the authors disagree with the conclusion that less skin irritation occurs when a composition having relatively neutral pH is topically administered. The examiner disagrees with the allegation that the skilled artisan would ignore the teachings in the secondary reference because, besides the fact that the reference clearly says exactly what it says, other authors would not agree. The examiner refers applicant to Baranda et al. (International Journal of Dermatology (2002); 41:494-499) - disclosing the correlation between pH and irritant effect - irritation Index (Irln) - of cleansers marketed for dry skin. On the basis of the results, the soaps tested were grouped into three categories: (1) soaps with a low Irln and pH near the neutral zone; (2) soaps with a high Irln and high pH ; and (3) products with the highest pH (> 11) and Irln (from 2.79 to 3.466) (Fig. 1). The correlation between these two parameters was statistically significant. Also see Figure 1 at page 496 which depicts the correlation

between the 2 parameters. The grouping of the products by pH and Irln clearly suggests that pH near neutral compositions have lower skin irritation when topically applied.

Claims 16, 19-22 and 28-30 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Basset et al. in view of WO 02/07520. **This rejection is maintained.**

Applicant alleges that the examiner made an unsupported argument that the pKa of compound, AG 18, is 7.24. Applicant has instead alleged that the pKa of AG 18 is 8.4 according to theoretical estimates. The examiner refers applicant to the STN Registry Database Property Data for AG 18 (submitted herewith). At page 3, the pKa for AG 18 is taught to be 7.24 +/- 0.18 (marked with an arrow). Therefore, the compound would indeed be non-dissociated and would be capable of acidifying the cell cytoplasm. As for the argument that one of ordinary skill would ignore the suggestion to neutralize the pH, the examiner again refers applicants to Baranda et al. (cited above).

Double Patenting

Claims 16, 19-22, and 28-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-18 and 20-23 of copending Application No. 11/408,056 in view Granstein Psoriasis (Further Evidence

of a Key Role for Leukocytes. J. Clin. Invest. Volume 98, Number 8, October 1996, 1695-1696).

Applicant argues that the application is in condition for allowance and, therefore, the rejection should be withdrawn. As is self-evident from the above, the examiner does not agree.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRIS E. SIMMONS whose telephone number is (571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/534,988
Art Unit: 1612

Page 7

/C. E. S./
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612